DEPARTMENT OF HEALTH AND HUMAN SERVICES

11-4-05
11-7-05

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Tetracycline Hydrochloride Soluble Powder

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by Cross Vetpharm Group Ltd. The ANADA provides for use of tetracycline hydrochloride soluble powder in the drinking water of calves, swine, chickens, and turkeys for the treatment and control of various bacterial infections.

DATES: This rule is effective [*insert date of publication in the* **Federal Register**].

FOR FURTHER INFORMATION CONTACT: John K. Harshman, Center for Veterinary Medicine (HFV–104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–9808, e-mail: *john.harshman@fda.gov.*

SUPPLEMENTARY INFORMATION: Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland, filed ANADA 200–374 that provides for use of TETRAMED 324 HCA (tetracycline hydrochloride), a soluble powder used in the drinking water of calves, swine, chickens, and turkeys for the treatment and control of various bacterial infections. Cross Vetpharm Group Ltd.'s TETRAMED 324 HCA is approved as a generic copy of Boehringer Ingelheim Vetmedica, Inc.'s TETRASURE 324 (tetracycline hydrochloride), approved

NFR1

under NADA 65–496. The ANADA is approved as of September 13, 2005, and the regulations are amended in § 520.2345d (21 CFR 520.2345d) to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In addition, FDA has noticed that certain withdrawal times for other approved generic products are not reflected in § 520.2345d. At this time, the regulations are amended to reflect the correct withdrawal times in calves and swine. This action is being taken to improve the accuracy of the regulations.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

FDA has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 520

Animal drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

■ 2. Section 520.2345d is amended by revising the section heading, paragraphs (a) through (c), the heading and introductory text of paragraph (d), and paragraphs (d)(1)(iii) and (d)(2)(iii) to read as follows:

§ 520.2345d Tetracycline powder.

(a) *Specifications.* Each pound of powder contains 25, 102.4, or 324 grams tetracycline hydrochloride.

(b) *Sponsors.* See sponsors listed in § 510.600(c) of this chapter for conditions of use as in paragraph (d) of this section:

(1) No. 000069: 25 grams per pound as in paragraphs (d)(3) and (d)(4) of this section.

(2) Nos. 000010 and 046573: 102.4 and 324 grams per pound as in paragraph (d) of this section.

(3) No. 053501: 102.4 and 324 grams per pound as in paragraphs (d)(1) and (d)(2) of this section.

(4) No. 046573: 102.4 and 324 grams per pound as in paragraph (d)(3) of this section.

(5) Nos. 051259, 057561, 059130, and 061623: 324 grams per pound as in paragraph (d) of this section.

(c) *Related tolerances.* See § 556.720 of this chapter.

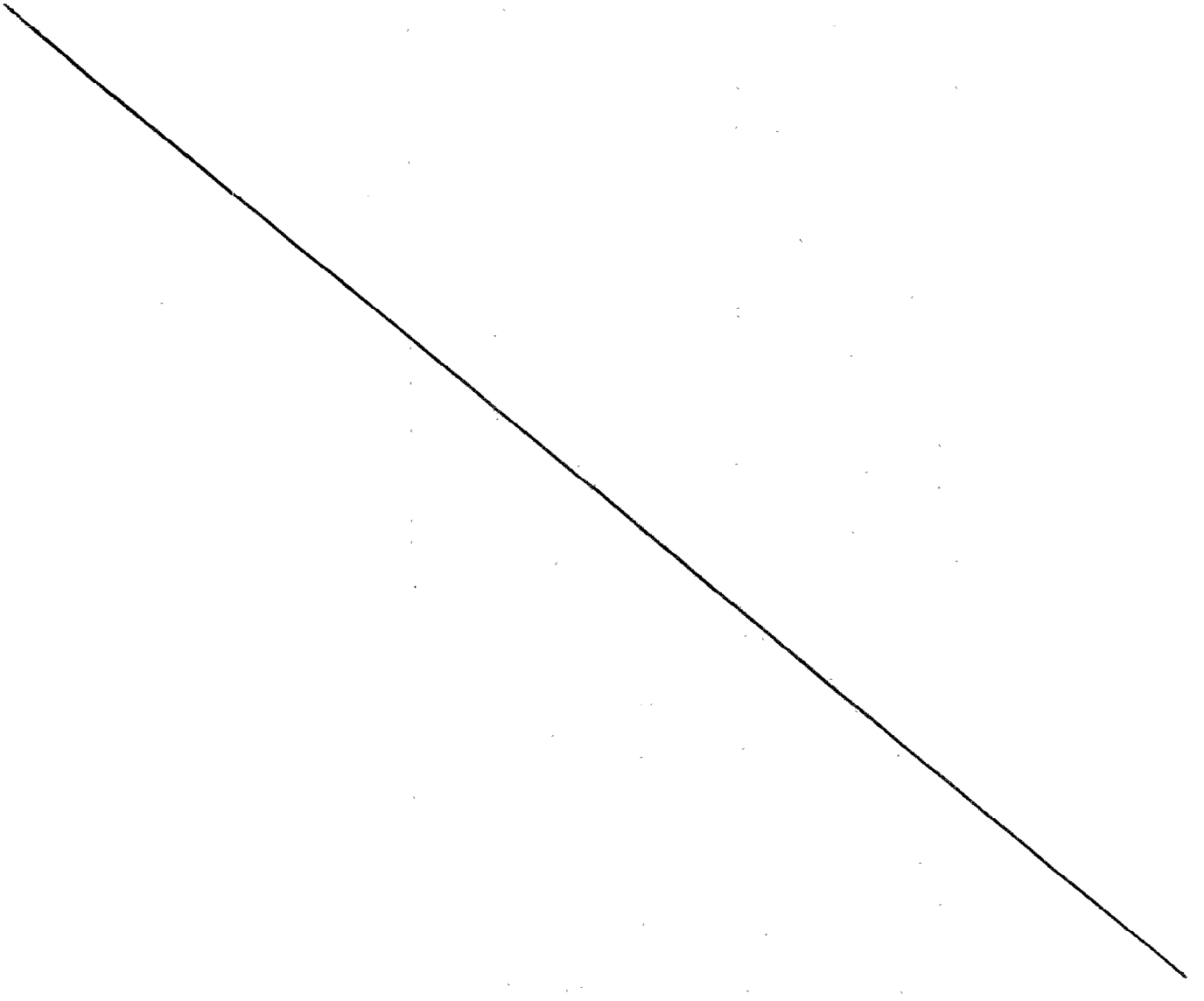
(d) *Conditions of use.* It is administered in drinking water as follows:

(1) * * *

(iii) *Limitations.* Administer for 3 to 5 days; do not slaughter animals for food within 4 days of treatment for sponsor No. 053501 and within 5 days of treatment for sponsor Nos. 000010, 046573, 051259, 057561, 059130, and 061623; prepare a fresh solution daily; use as the sole source of tetracycline. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

(2) * * *

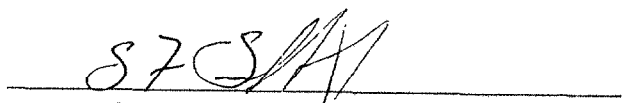
(iii) *Limitations.* Administer for 3 to 5 days; do not slaughter animals for food within 7 days of treatment for sponsor No. 053501 and within 4 days



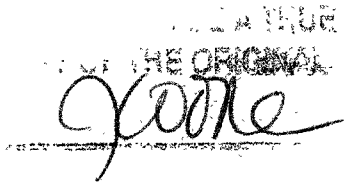
of treatment for sponsor Nos. 000010, 046573, 051259, 057561, 059130, and 061623; prepare a fresh solution daily; use as the sole source of tetracycline.

* * * * *

Dated: 10/19/05
October 19, 2005.



Stephen F. Sundlof,
Director,
Center for Veterinary Medicine.



[FR Doc. 05–????? Filed ??–??–05; 8:45 am]

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